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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,775	04/12/2002	Peter J. W. Sterk	08698.0001	9919

7590 12/17/2003  
Finnegan Henderson Farabow  
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Washington, DC 20005

EXAMINER

SAUCIER, SANDRA E

ART UNIT PAPER NUMBER

1651

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/019,775

Applicant(s)

STERK, PETER J. W.

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6/10/02 .                      6) ☐ Other: \_\_\_\_\_

#### DETAILED ACTION

Claims 1-4 are pending. Claims 1-3 are under examination.

#### Election/Restriction

Applicant's election of species, fibrinogen glue, is acknowledged. It is correct that applicant may claim the subject matter that they choose. However, an election of species means that there is more than one patentable species in the claims and that the elected invention will be examined first and if no art is found against the first species, the next species will be examined, etc. as indicated in MPEP §803.02, so that if no art can be applied, the generic claim may be indicated to be allowable. Applicant is not forced to carve up the invention in the absence of applicable art and an election of species is not a refusal on the part of the Office to examine the claims. Applicant's urge that unnecessary delay and expense and duplicative examination will be avoided by the examination of all species. However, no argument is put forward that is persuasive of error in requiring the election of species for examination purposes.

#### Claim Rejections – 35 USC § 112

##### INDEFINITE

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Use of "i.e." in claim 1 is indefinite because it is unclear if the phrase is intended to further limit the claim.

Use of the phrase "as well as" constitutes an improper Markush group.

What is the meaning of a foodstuff-dye? Is this a dye derived from foodstuff or a dye approved by some authority for use in foodstuffs.

### Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1–3 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wright *et al.* [U] or Nasaduke *et al.* [V] or US 5,292,362 [A].

The claims are directed to a composition comprising a solution of fibrinogen and a dye such as indocyanine green.

The references are relied upon as explained below.

Wright *et al.* disclose a composition comprising a liquid fibrinogen and indocyanine green (Materials and Methods).

US 5,292,362 disclose in Table 8, a composition comprising a liquid fibrinogen 70% and indocyanine green 0.5%.

Nasaduke *et al.* disclose a composition comprising fibrinogen, thrombin and dyes, methylene blue and fluorescein (Materials and Methods).

### Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,292,362 [A] or Nasaduke *et al.* [V].

The claim is directed to a composition of liquid fibrinogen and various dyes.

The references are relied upon as explained below.

US 5,292,362 generically disclose the addition of chromophores to the adhesive composition (col. 11, l. 18). Also disclosed is the addition of exogenous chromophores to facilitate visualization of tissue sealing compositions.

Nasaduke *et al.* disclose that the addition of dyes to a fibrin sealant composition permits accurate visualization of the sealant at time of surgery (p. 325).

The substitution of any physiological suitable chromospheres for the chromophores in the fibrin sealant compositions taught by US 5,292,362 or Nasaduke *et al.* would have been obvious because '362 generically teaches such additions and both references teach that the addition of a dye permits visualization of the fibrin sealant during surgery.

One of ordinary skill in the art would have been motivated at the time of invention to make substitution of chromophores to a fibrin sealant in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.


To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal

Application/Control Number: 10/019,775  
Art Unit: 1651

Page 5

work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish at the end.

Sandra Saucier

Primary Examiner

Art Unit 1651

December 10, 2003